Early Childhood Obesity Risk-Reduction Program in Hispanics (ECOR-H)

IRB # 16-0164-P2H, NIH #CC-HD-16-127

NCT ID (not yet assigned)

Study Start: March 10, 2016

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☐ **Control Group** **STUDY PROGRESS CHECK LIST** ☐ **Intervention Group**

NAME:_____ ID#_____

1. At recruitment time 30 weeks pregnancy Baseline T-1 Survey interview:

☐ Eligibility Form

☐ Consent Form

☐ Contact Form

☐ Protocol for Participant Safety

Surveys:

☐ Demographic and Reproductive Characteristics

☐ Depression: Edinburgh Postnatal Depression Scale

☐ Quality of Primary Intimate Relationship

☐ Infant Feeding Intention Scale

☐ Adapted Version Breastfeeding Knowledge

☐ Signed Notice of Payment

☐ Next Visit Date _____

2. Pre-Birth Interview at 37 weeks of pregnancy T-2 Survey interview:

☐ Protocol for Participant Safety

☐ Infant Feeding Intention Scale

☐ Adapted Version Breastfeeding Knowledge

☐ Signed Notice of Payment

☐ Estimated Infant Birthdate:_____

3. Review of Mother/Infant Chart T-3 online UK Hospital Medical Records

☐ Review of mother/Infant Chart

☐ Next Visit Date at home infant age 2 to 4 weeks old_____

4. Perinatal Interview at Infant's age 2 to 4 weeks old at participant's home

□ Protocol for Participant Safety

□ Protocol for Mastitis

□ Depression: Edinburgh Postnatal Depression Scale

□ Quality of Primary Intimate Relationship

□ Breastfeeding Self efficacy Short Scale

□ Infant Feeding Assessment

□ Infant Anthropometric Measurements

□ Mother's weight

□ Signed Notice of Payment

□ Next Visit Date at home infant age 3 months old_____

5. 3 Months Old Infant Follow Up at participant's home

□ Protocol for Participant Safety

□ Protocol for Mastitis

□ Breastfeeding Self efficacy Short Scale

□ Infant Feeding Assessment

□ Infant Anthropometric Measurements

□ Mother's weight

□ Signed Notice of Payment

□ Next Visit Date at home infant age 4 months old_____

6. 6 Months Old Infant Final Follow Up at participant's home

- Protocol for Participant Safety
- Protocol for Mastitis
- Quality of Primary Intimate Relationship
- Breastfeeding Self efficacy Short Scale
- Infant Feeding Assessment
- Infant Anthropometric Measurements
- Mother's weight
- Acceptability of the Intervention (only for intervention group)
- Signed Notice of Payment

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Home visits protocol

Participants in this study may choose either the University of Kentucky Polk-Dalton Clinic located at 217 Elm Tree Lane, Lexington, Kentucky; the University of Kentucky, College of Nursing located at 315 CON Building, UK campus; or their home to run procedures such as data collection and/or intervention sessions. This is the protocol in case the participant choose a home visit.

1. **Data Collection home visits Protocol: The home visit will be schedule at date and time of participant convenience.**

- Greeting and check to see if is a good day
- Identified today activity
- Read protocol of disclosing violence and/or depression (see Protocol for Participant Safety)
- Apply survey
- During postpartum visits T-4, T-5, T-6 we will collect infant growth measurement and mother's weight. To do this the research staff (RS) will follow the anthropometry procedures manual from CDC to capture the weight, length, head and chest circumference of the infant (see Anthropometric Measurements Protocol). A digital baby scale (SECA) will be used to weigh the infant. Length will be measured using an infant measure mat (Infantometer). A disposable measurement will be used for head and chest circumferences.
- The mother's weight will be collected using a weight scale (Tanita).
- **Always tell the participant what you are going to do before you do it.**

2. **Time allocated for data collection**: The following table explained the amount of time allocated for each data collection encounter:

Procedures and Encounters	**Control Group Estimate Time**
Baseline Interview	30 minutes
Pre-Birth interview	15 minutes
Chart Review	0 minutes
Perinatal Interview	20 minutes
3 months Follow-up	15 minutes
6 months follow-up	15 minutes
Total time	**95 minutes = 1h 35m**

Research Staff: Mily Ralsten is bilingual fluent in both, English and Spanish and bicultural. She is trained in human subject (CITI) and has additional training in cultural competence. Mrs. Ralsten has extended experience conducting research with the Hispanic population in the United States. Additionally, Dr. Ana Maria Linares, DNS, RN, IBCLC (PI) is supervising all research personnel to assure that they follow the high standard of the study protocol.

3. **Intervention sessions**: intervention session will be scheduled in the following times in mutual agreement between the Peer Counselor and the participant.

Procedures for Intervention

Step	Procedure	Time period	Estimate Time
Step 1	1st Individual face-to-face session	After study enrollment during pregnancy	45 minutes
Step 2	2 Follow-up phone calls	During pregnancy	30 minutes total
Step 3	1st Postpartum visit at the Hospital	About 1-2 days after the birth of your infant	30 minutes
Step 4	2nd Postpartum visit at your home	After discharge at your convenient	30 minutes
Step 5	3 Follow-up phone calls	Participant at home	45 minutes total
Step 6	3rd Postpartum visit at your home	Participant at home	30 minutes
Step 7	Other Phone calls		30 minutes total
Total			240 minutes = 4 hours

Intervention session will follow the fidelity index protocol (see Intervention Session Summary) and the PI will get the report after each session.
The peer counselor, Karina Alvarez is a local bicultural/bilingual community woman who has successfully breastfed, has received training in breastfeeding education, and will work with their peers to improve breastfeeding outcomes. The training was provided for Dr. Linares (PI) an International Board Certified Lactation Consultant. The PI used the Peer Counseling Training Platform from United Stated Department of Agriculture (USDA) to train the PC (https://lovingsupport.fns.usda.gov/content/peer-counseling-training). The PC and IBCLC (PI) will discuss the individualized components of the intervention during weekly meetings.

Protocol for participant safety

NOTE TO RESEARCH INTERVIEWER: Participant SHOULD BE INTERVIEWED IN A PRIVATE ROOM ALONE.

Read the following text to a woman that is going to complete the Edinburgh Post Natal Depression Scale (EPDS).

- As you are pregnant or have recently had a baby, we would like to know how you are feeling.
- If you obtain a score indicating possible depression, you will be referred to the clinic for adequate management and we will follow-up your progress.
- If during our assessment you tell me that a child in your home is being abused or you tell me that your husband is physically or sexually abusing you, this worries me. Please know that I am required by Kentucky State Law to report this abuse to the Kentucky Cabinet for Health and Family Services.
- The purpose of this report is to help you find out about services available in the community.
- I will refer you with the Social Worker of the institution where you are receiving Prenatal Care, who will help you in this process.
- The Social Worker will make a call with you to the Kentucky Cabinet for Health and Family Services; so that you can talk with them about the services you may want or need.
- You may refuse services.
- I can also tell you about these services and help you contact these agencies when you are ready.
- For your safety your husband/partner will not be informed that this report has been made.
- We will follow-up your progress with the Social worker to assure your adequate treatment.

Appendix D (English)

Protocol for assessment of symptoms of Mastitis

Please tell me if you have any of the following symptoms:

Breast

- Red, swollen and painful area in the affected breast
- Skin may appear shiny and tight with red streaks

General

- Flu-like symptoms: lethargy, headache, myalgia, nausea and anxiety
- Fever (temperature >38°C or 100.4°F)

- If the participant presents any of these symptoms, notify immediately to the IBCLC at 859 967 6893 and/or send participant to triage or health provider.

Data Analysis: Descriptive analysis of the study data will be accomplished using means and standard deviations or frequency distributions. This will not only summarize the variables but will assist in identifying missing or out-of-range values so they can be corrected. Differences in demographic and personal characteristics between the intervention and usual care groups will be assessed using two-sample t-tests, Mann-Whitney U tests, or chi-square tests of association; this will serve as a test of whether the randomization yielded comparable groups from this population. To answer the research questions associated with Aim #1, descriptive summaries will be used. A careful timeline will be kept to assess whether all 40 participants are enrolled and randomized within the time dedicated to recruitment (RQ #1). The percent of treatment group participants who complete all intervention sessions (RQ #2) will be determined from the log of intervention attendance that will track each treatment group participant's attendance over time. To assess the percent of enrolled participants who remain in the study through the conclusion (RQ #3), participation status at each time-point will be tracked for each participant; percent of completers will be the number of those who complete all assessments divided by 40. The number of participants remaining at the end of the study from the original 20 enrollees in the intervention group will be assessed as one objective measure of feasibility and acceptance of the intervention. In addition, one instrument will be included during the final interview with the mothers that will measure acceptability of the intervention. These data will be summarized quantitatively using descriptive statistics to give an overall group response of acceptability of the developed intervention. For Aim #2 we will determine whether treatment group is associated with outcomes of interest and whether type of infant feeding is associated with infant growth and body composition. The two treatment groups will be compared on maternal and child outcomes, including intention and self-efficacy, initiation and maintenance of EBF, and time to introduction of complimentary foods, using two-sample t-tests, Mann-Whitney U tests or chi-square tests. Infants who are exclusively breastfed will be compared with infants who have formula along with breastmilk to assess whether there are differences in growth and body composition between the groups. This analysis will be based on two-sample t-tests. While the expected level of power for these group comparisons is limited to detect all but large effect sizes, we will use these results not only as preliminary group comparisons, but also to estimate effect sizes for future studies.